

CYNTHIA A. HARDING, M.P.H. Interim Director

JEFFREY D. GUNZENHAUSER, M.D., M.P.H.

Interim Health Officer

313 North Figueroa Street, Room 708 Los Angeles, California 90012 TEL (213) 240-8156 • FAX (213) 481-2739

www.publichealth.lacounty.gov

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March 10, 2015

TO: Each Supervisor

FROM: Cynthia A. Harding, M.P.H.

Interim Director

SUBJECT: OUTBREAKS OF MULTIPLY-RESISTANT BACTERIAL INFECTIONS

FOLLOWING ENDOSCOPIC PROCEDURES AT TWO LOS ANGELES COUNTY

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MEDICAL CENTERS

This memorandum is to provide an update on the outbreaks of multiply-resistant bacterial infections caused by carbapenem-resistant *Enterobacteriaceae* (CRE) following endoscopic procedures at two medical centers located in Los Angeles County (LAC). We also provide a general description of CRE and potential disease transmission through endoscopes as well as LAC Department of Public Health (DPH) surveillance and monitoring efforts.

Background

On February 24, 2015, the LAC DPH was informed by Cedars-Sinai Medical Center of four patients with CRE infections following endoscopic retrograde cholangiopancreatography (ERCP) procedures. This follows an outbreak reported to LAC DPH on January 28, 2015, of seven cases of CRE infections associated with ERCP at Ronald Reagan University of California, Los Angeles (UCLA) Medical Center. Two UCLA patients and one Cedars-Sinai patient died; for the latter, the CRE infection was successfully treated and probably did not contribute to the death. Both outbreaks were only identified by extensive and detailed records review at the two medical centers and were immediately reported to LAC DPH once they were detected. LAC DPH investigation began within one day of the initial reports and included review of clinical and laboratory information, a site visit by LAC DPH staff and, following consultation with the California Department of Public Health (CDPH) and the Centers for Disease Control and Prevention (CDC), recommendations to prevent additional infections. When the outbreaks were identified, the affected hospitals immediately removed the duodenoscopes (a specific type of endoscope) used on the infected patients to prevent further risk. By February 18, 2015, UCLA had notified other patients who had an ERCP with the implicated duodenoscopes; to date, no additional illness has been identified. Notification currently is being done by Cedars-Sinai to determine whether others may have been affected.

CRE include several types of bacteria that may colonize the intestines and are resistant to most, and sometimes all, available antibiotic drugs. ERCP is a procedure where a duodenoscope is passed through the mouth and stomach into the upper part of the intestine where it is used to evaluate and in some cases treat serious liver and pancreatic disease. If CRE contaminate the scope and are not eliminated during the cleaning

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and disinfection process after each use, they may cause infection or gastrointestinal colonization in subsequent patients who have the procedure. LAC DPH staff observed duodenoscope reprocessing at both Cedars-Sinai and UCLA and found no breaches with practices to prevent the spread of infections. Previous outbreaks reported by the CDC indicated that the design of the duodenoscope is such that all bacteria may not be eliminated by cleaning - even when all of the manufacturer's recommended guidelines are strictly followed. Similar ERCP-associated CRE outbreaks have been reported from several large cities and the Food and Drug Administration (FDA) has received over 75 Medical Device Reports regarding this problem. Currently, FDA and CDC are considering approaches to improve the effectiveness of reprocessing. In the interim, both Cedars-Sinai and UCLA have taken additional steps to enhance patient safety which DPH deems to be appropriate.

The CRE outbreaks at Cedars-Sinai and UCLA are not threats to public health. However, the spread of CRE is an emerging public health concern, as the vast majority of infections occur in persons who never have an ERCP and mortality from CRE is high. In 2010-2012, LAC DPH mandated reporting of CRE from all LAC hospital laboratories. During that two-year period, 2,121 CRE infections were reported from 83 of 102 acute care hospitals, including 9 long-term acute care facilities and many skilled nursing facilities. Most CRE infections are nosocomial (i.e., transmitted in a healthcare setting) or occur in people with recent exposure in a healthcare facility. Both the prior use of antibiotics as well as hospital stays that are lengthy or complicated increase the risk of acquiring CRE.

Prevention and Treatment of CRE Infections

The risk of CRE infections associated with ERCP can be reduced but not eliminated by strictly adhering to manufacturer-recommended processes for cleaning and disinfecting duodenoscopes. Additional measures such as ethylene oxide sterilization are being considered as strategies that may further reduce the risk. Approaches to reduce the spread of CRE include good infection control practices in all healthcare facilities (e.g., hospitals, long-term care facilities, and skilled nursing facilities), judicious use of antibiotics, and early detection so that specific precautions can be taken. Treatment of CRE infections is challenging because they are resistant to multiple antibiotics. Therefore, choices of therapy should be guided by laboratory testing results.

Impact on LAC

Results from prior surveillance suggest that the high occurrence of CRE infections on the West Coast is concentrated in LAC. Although CRE infections are still relatively uncommon, interventions are needed to slow their spread. While several thousand ERCP procedures are performed at LAC hospitals each year, no ERCP-associated CRE events other than the two outbreaks recently noted at UCLA and Cedars-Sinai have been reported.

DPH Response Actions

LAC DPH has taken the following steps in response to the ERCP-associated outbreaks and emerging threat of CRE infections:

1. On January 28, 2015, DPH staff initiated an investigation of the outbreak at Ronald Reagan UCLA Medical Center and on February 25, 2015, initiated an investigation at Cedars-Sinai Medical Center. DPH staff have worked with both facilities and coordinated with the CDPH and CDC to ensure that appropriate actions have been taken to prevent further ERCP-associated infections at these medical centers.

- 2. As part of the investigation, the DPH Public Health Laboratory (PHL) performed molecular testing of the Cedars CRE isolates to determine that they were highly related and likely came from a common source.
- 3. DPH continues to communicate with UCLA and Cedars-Sinai Medical Centers regarding the results of the outreach and cultures done on other patients who had had ERCP procedures with the implicated duodenoscopes.
- 4. On February 27, 2015, DPH sent a letter to all hospitals in LAC informing them of the potential risk of CRE infection after ERCP and requested that the facilities review their records to determine whether any cases had occurred. In addition, DPH recommended that hospitals prospectively identify any CRE infections after ERCP and report all cases and clusters to DPH.
- 5. DPH physicians are available 24/7 to consult with hospitals about CRE following ERCP and other infections caused by CRE.
- 6. DPH is participating in weekly conference calls with CDPH, CDC and FDA to discuss the ongoing challenges of CRE following ERCP procedures and potential new guidance to reduce risk.
- 7. In 2014, LAC DPH was one of eight health departments nationwide to receive five-year funding from CDC to study and reduce the spread of CRE infections. Laboratory-based surveillance is being established and DPH PHL will receive and test isolates from participating facilities. Studies will focus on the potential for spread of CRE across healthcare networks and between skilled nursing facilities, long-term acute care centers and hospitals. Prevention recommendations will be made and impacts assessed.

If you have any questions or need additional information, please let me know.

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c: Interim Chief Executive Officer
County Counsel
Acting Executive Officer, Board of Supervisors